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| 10/758,455 | 01/15/2004 | Charles O. Townley | THUMB-604DIV | 5634 |

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| EXAMINER |
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PAPER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/758,455
Filing Date: January 15, 2004
Appellant(s): TOWNLEY, CHARLES O.

Christopher Rudy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/8/08 appealing from the Office action mailed 8/2/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Application No. 09/352472.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| | | |
|-----------|------------|--------|
| 5,507,818 | McLaughlin | 4-1996 |
| 2,934,065 | Townley | 4-1960 |

| | | |
|-----------|---------------|---------|
| 5,871,547 | Abouaf et al. | 2-1999 |
| 5,674,297 | Lane et al. | 10-1997 |

Wright Medical Technology- "Swanson Titanium Basal Thumb Implant"
ASTM F 1377-98 "Standard Specification for Coabalt 28 Chromium-6
Molybdenum Powder for Coating of Orthopedic Implants" 1998, pp. 699,700.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 21,22,25,26,28,29,40,41 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin (5507818). Fig. 1 shows a modular joint prosthesis having a stem **13** and a head **12** attached to the stem. As seen in the drawing the angle of projection of the stem from the head is acute. Fig. 3 illustrates an eccentric attachment of the head to the stem. McLaughlin's eccentric attachment includes a middle wedge shaped connector **11** having an angled receptacle **22** for a trunion that can be construed as eccentric and offset from the center of the generally planar end of the head. Fig. 3 also illustrates the head **12** having a generally hemispherical articulating surface and an abrupt planar end with a trunion receiving cup **22**. It can also be seen that the stem **13** has a trunion **21**. McLaughlin does disclose the prosthesis can be used for any joint by preparing two articulating surfaces to receive the implant, (col. 1, lines 26-28) and is not limited to that listed (col. 2, lines 1,2). However, McLaughlin fails to explicitly disclose the joint of repair is the thumb. It would have been obvious to one of ordinary skill in the art to use a head of a size for a correspondingly

prepared trapezium bone stock and a stem of a size for intrameduallary insertion in metacarpal bone stock for the implant of McLaughlin since one of ordinary skill in the art would understand that the body is made up of many joints and that when the thumb joint has been injured or diseased it would be desirable to replace with a prosthesis.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin '818 in view of Townley (2934065). McLaughlin is explained supra. However, McLaughlin fails to disclose the flanged stem profile. Townley teaches (Fig. 3) a stem having a tri-flange cross-section. Townley also teaches this is to preserve bone structure and prevents rotation of the stem in the bone, col. 4, lines 60-63. It would have been obvious to one of ordinary skill in the art to use the triflange stem profile as taught by Townley with the prosthesis of McLaughlin to better secure the stem in the bone canal such that it does not move while in the patient.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin '818 in view of Lane et al. (5674297). McLaughlin is explained supra. However, McLaughlin fails to disclose an inwardly curved stem. Lane teaches (Figs. 4,7) a stem **52** having an inward curve. It is well known in the art that the curvature of a prosthetic stem is to match the curvature of the bone. It would have been obvious to one of ordinary skill in the art to use the inward curve profile as taught by Lane et al. for the stem of McLaughlin to better match the contour of the bone canal such that it does not cause any uneven stress distribution to cause an unwanted fracture.

Claims 31,32,34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin '818 in view of Abouaf et al. (5871547). McLaughlin is explained

supra. However, McLaughlin fails to disclose the head is ceramic or to utilize a Morse taper to couple the head and stem. Abouaf et al. teach (Fig. 1) a modular prosthesis having a stem with a trunion that is tapered and a head with a receptacle that is tapered to match the trunion. Abouaf also teaches to utilize different materials, such as ceramic for articulating heads of joints because of its toughness, col. 4, lines 7,29-31,38-42. Abouaf additionally discloses the implant can have a metal stem and ceramic head (col. 6, lines 44-51) that are assembled via the Morse taper. It would have been obvious to one of ordinary skill in the art to utilize a ceramic head and an alternative coupling, such as a Morse taper for the trunion of the metal stem as taught (col. 3, lines 61, 63, 65) by Abouaf et al. with the thumb implant of McLaughlin such that the prosthesis has reduced wear at the joint or articulating area and provides an easy coupling to match the trunion and cup.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin '818 in view of Wright Medical Technology. McLaughlin is explained supra. However, McLaughlin fails to disclose a head having a diameter of 13mm-19mm. The Swanson thumb implant can have a head with a diameter greater than 13mm, page 2. It would have been obvious to one of ordinary skill in the art to use a head having a diameter greater than 13mm as taught by Wright Medical Technology with the prosthesis of McLaughlin such that it properly fits the patient's anatomical dimensions.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin '818 in view of (ASTM, 1998). McLaughlin is explained supra. However, McLaughlin fails to disclose a porous coating on the prosthesis. The ASTM teaches that

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porous coatings can be applied on prostheses to improve tissue attachment and also bonding of cements to the prostheses, p. 700. It would have been obvious to one of ordinary skill in the art to incorporate a porous coating on the prosthesis of McLaughlin such that it enhances the attachment of the prosthesis in the implanted site as taught by the ASTM.

(10) Response to Argument

The Appellant's argument against the prior art is that first McLaughlin teaches a joint implant that is "large" and cannot be reduced in size to fit in a thumb. In response the Examiner would like to state this is just an opinion and the dimensions that are alleged to be "large" have no basis to compare them to. To describe an element as "large" must have some standard in order to compare an element or component to. Claim 21 sets forth no dimensions and gives no basis as to whom the recipient of the implant would be for, such that while an implant may be too large for one patient it *may not necessarily be large enough for another*. For example, a child or infant has a tiny hand, however, someone like Andre the Giant requires an extremely large implant structure for his hand, thus there is no merit in Appellant's argument that the implant is too large since that is not necessarily the case for all patients. Large describes an object when it has something to compare it with. In this case there is nothing in McLaughlin that states the implant is too large for a thumb, this is mere speculation. Second the Appellant states the head of McLaughlin's implant does not articulate. In response to appellant's argument that the head is not capable of articulating, a recitation

of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Clearly, the rounded or hemispherical head is fully capable of articulation.

In response to Appellant's argument that the head of McLaughlin is discontinuous as to its sphericity, the Examiner disagrees since the head clearly maintains a dome shape and it can be said it maintains its sphericity.

In response to appellant's argument that the references fail to show certain features of appellant's invention, it is noted that the features upon which appellant relies (i.e., the head being directly attachable or in contact with the stem trunion) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Appellant argues that McLaughlin has intervening structure to attach the head and stem. In response to Appellant's argument that McLaughlin includes additional structure not required by Appellant's invention, it must be noted that McLaughlin discloses the invention as claimed. The fact that it discloses additional structure not claimed is irrelevant to the issue of patentability.

Appellant then argues that the attachment of the head and stem cannot be considered eccentric. However, the Examiner respectfully disagrees since the attachment locations of the head and the stem are clearly offset from one another since

the intervening structures extend the head away from the distal stem as seen in Figs. 1,3 of McLaughlin and thus can be considered eccentric. Appellant presents this argument with respect to claim 25, but it should be noted that the claim does not require a direct attachment and thus the attachment between the head and stem is offset and is considered to be eccentric.

Appellant's argument to claim 22 is that the stem of McLaughlin is attached to the distal stem at a perpendicular angle and not an acute angle. This is only accomplished if there is a direct attachment between the stem and head. The claim does not state the head requires to be directly attached and thus Appellant's argument is moot. McLaughlin clearly illustrates an acute angle with the use of the intervening structure.

Appellant's argument regarding claim 26 is that McLaughlin does not have the claimed features of either a flanged or curved stem or an eccentric attachment. However, as mentioned above with respect to claim 25, McLaughlin clearly establishes an eccentric attachment.

Claim 28 is argued to not have a trunion receiving cup for a trunion on the stem. However, it should be noted that the claim requires a trunion on the stem and a trunion receiving cup in the head. The claim does not require the trunion of the stem to be directly received in the trunion receiving cup of the head. Clearly a trunion is received in the head of the device and the trunion of the stem is clearly received in a trunion receiving cup. The trunion of the stem is fully capable of being received in the trunion receiving cup of the head.

Claim 29 is argued in that the combination of the claimed features found in McLaughlin's device causes it to be inoperable. In response to appellant's argument that the stem trunion cannot be received in the receiving cup of the head, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 40, Appellant's arguments state the device of McLaughlin cannot be sized for use in a thumb. However, sizing the implant for configuration in the thumb is well within the skills of an expert in the field of orthopedic surgery. Additionally, the size is relative to the patient receiving the implant. The claims do not set forth and limits and it should be noted that in a decision regarding *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Additionally, it should be mentioned again what may be too large for one patient may be of the right size for another. Not all patients have the same physical or anatomical dimensions.

Appellant argues that claim 41 is not met by McLaughlin stating that the angle of attachment between the head and stem is not acute. In response to Appellant's

argument that McLaughlin includes additional structure (intervening connectors) not required by Appellant's invention, it must be noted that McLaughlin discloses the invention as claimed. The fact that it discloses additional structure (connectors that result in providing an acute angle of attachment between the stem and head) not claimed is irrelevant to the issue of patentability.

In response to appellant's argument that Townley is nonanalogous art and cannot be combined with McLaughlin, it has been held that a prior art reference must either be in the field of appellant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the appellant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Townley clearly provides a relevant teaching in providing a firm attachment to bone by using the tri-flange. A person of ordinary skill would clearly look at ways bone implants are secured into canals of the bone bodies, regardless of what bone it is.

In response to appellant's argument that Lane is also nonanalogous art, it has been held that a prior art reference must either be in the field of appellant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the appellant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Lane is used as a teaching with McLaughlin to provide the implant with a curved stem to match that of the bone. Appellant argues the joint implant of Lane operates differently than other joint. However, this a moot point since the Examiner was not

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taking a teaching of how the device of Lane operates. The teaching was only to provide a curved stem, Changing the curvature of the stem of McLaughlin's implant would not materially affect the operability of the device.

In response to appellant's argument that Abouaf is nonanalogous art, it has been held that a prior art reference must either be in the field of appellant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the appellant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Abouaf clearly is relevant in that it provides a teaching to improve durability of the implant by using certain materials, i.e. ceramic and also improve the coupling by having it as a Morse taper. The combination of McLaughlin with Abouaf would not alter the operability of the device and the argument is not persuasive.

Appellant argues claim 37 cannot be rejected over McLaughlin in view of Wright technology stating they are different devices. The fact that the Swanson implant is one piece is irrelevant since the teaching used was the size dimensions, thus the combination is proper.

Claim 42 is argued by Appellant that the material teaching from (ASTM) to place a ceramic coating on an orthopedic device is not combinable with McLaughlin. However, the claim does set forth any specific location as to where the coating is required, thus to apply the ceramic coating on any location would enhance the attachment to bone and thus McLaughlin can be combined with the ASTM teaching.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738

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TQAS TC 3700

